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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,934	03/24/2004	Jason R. Fink	58211US004	5151

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EXAMINER

WOODWARD, CHERIE MICHELLE

ART UNIT PAPER NUMBER

1647

DATE MAILED: 12/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/807,934	FINK ET AL.	
	Examiner	Art Unit	
	Cherie M. Woodward	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 3,4 and 8-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2 and 5-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Formal Matters

1. Applicant's amendments, filed 28 September 2006, are acknowledged and entered. Claims 1-21 are pending. Claims 3-4 and 8-21 are withdrawn from consideration as being drawn to non-elected inventions. Claims 1-2 and 5-7 are under examination. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections/Objections Withdrawn

2. The rejection of claims 1-2, and 5-7 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identifying a compound that selectively modulates at least one cellular activity mediated by human TLR7, does not reasonably provide enablement for a method of identifying a compound that selectively modulates at least one cellular activity from other TLRs, is withdrawn in light of Applicant's amendments.

3. The rejection of claims 1-2 and 5-7 under 35 U.S.C. 102(a) as being anticipated by Medzhitov et al., (US 2003/0023993, published 30 January 2003, now US Patent 6,960,343, 1 November 2005) is withdrawn in light of Applicant's amendments.

4. The rejection of claims 1-2 and 5-7 under 35 U.S.C. 102(e) as being anticipated by Medzhitov et al., (US Patent 6,960,343, 1 November 2005, benefit to 9 May 2001) is withdrawn in light of Applicant's amendments.

5. The rejection of claims 1-2 and 5-7 under 35 U.S.C. 102(e) as being anticipated by Beutler et al., (US Patent 7,029,861, 18 April 2006, benefit to 15 September 1998) is withdrawn in light of Applicant's amendments.

6. The rejection of claims 1-2 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because the term "different extent" in claim 2 is a relative term which renders the claim indefinite, is moot in light of the new grounds for rejection. See below.

Claim Rejections/Objections Maintained

Provisional Obviousness-Type Double Patenting

7. The provisional rejection of claims 1-2 and 5-6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 9 and 22 of copending Application No. 10/788731, is maintained for the reasons of record in the Office Action of 28 June 2006 and for the reasons stated herein. Applicant has failed to file the required terminal disclaimer or otherwise cancel or amend the claims around the cited copending application.

Claim Rejections - 35 USC § 112, Second Paragraph

8. The rejection of claims 1-2, and 5-7 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because the terms “at least one cellular activity,” “cellular activity,” “first cellular activity,” “second cellular activity,” and “TLR-mediated cellular activity” fail to limit the thousands of activities of cells, such that the metes and bounds of the term can be ascertained by one of ordinary skill in the art, the terms are not defined by the claim, and the specification does not provide a standard for ascertaining the requisite degree, is maintained for the reasons of record in the Office Action of 28 June 2006 and for the reasons stated herein.

Applicant argues that the claims have been amended to provide clarity. Applicant’s argument has been fully considered, but is not persuasive.

Although the claims have been amended to recite “at least one TLR7-mediated cellular activity”, “a TLR7-mediated cellular activity”, “a first TLR7-mediated activity”, “a second TLR7-mediated cellular activity”, the metes and bounds of what those activities may entail are not supported in the disclosure and are not all known in the art.

9. The rejection of claims 1-2 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because the term “selectively modulates” in claims 1-2 is a relative term which renders the claim indefinite is maintained for the reasons of record in the Office Action of 28 June 2006 and for the reasons stated herein.

Applicant argues that the claims have been amended to provide clarity. Applicant’s argument has been fully considered, but is not persuasive.

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Although the claims have been amended to some extent, the claims still recite the term “selectively modulates” which is indefinite because the requisite term of degree of modulation and the extent of the selectivity are not disclosed in the specification and uncertain in the art.

New Claim Rejections/Objections – Necessitated by Amendment
Provisional Obviousness-Type Double Patenting

10. Claims 1-2 and 5-7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 9, 13, 14, 22, 39, and 40 of copending Application No. 10/788731. Applicant’s amendments bring additional claims of the copending Application No. 10/788731 under the provisional obviousness-type double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112, Second Paragraph

11. Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the phrase "at least about two-fold greater." The metes and bounds of the phrase cannot be ascertained because no benchmark is given, the range is not defined by the claim, and the specification does not provide a standard for ascertaining the requisite degree of the range.

12. Claims 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 recites the phrase "target modulation profile." There is no support in the disclosure such that one of ordinary skill in the art would understand what Applicant means by a "target modulation profile." The metes and bounds of the phrase cannot be ascertained and the specification does not provide a standard for ascertaining what the target modulation profile might be.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 1-2 and 5-7 are rejected under 35 U.S.C. 102(a) as being anticipated by Jurk et al., (Nature Immunology. 2001 Aug; 3(6):1) (reference cited on Applicant's IDS, filed 13 August 2004).

The claims recite a method of identifying a compound that selectively modulates at least one ILR7-mediated activity of a plurality of TLR7-mediated cellular activities, the method comprising contacting a test compound with at least one cell having a first TLR7-mediated cellular activity and detecting modulation of the first TLR7-mediated cellular activity, contacting a test compound with at least one cell having a second TLR7-mediated cellular activity and detecting modulation of the second TLR7-mediated cellular activity and identifying the test compound as a compound that selectively modulates at least one TLR7-mediated cellular activity of a plurality of TLR7-mediated cellular activities

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if the test compound modulates the first TLR7-mediated cellular activity to an at least about two-fold greater extent than it modulates the second TLR7-mediated cellular activity; wherein the test compound modulates the first TLR7-mediated cellular activity and does not modulate the second TLR7-mediated cellular activity; a method of identifying a target compound having a target modulation profile of TLR7-mediated cellular activities comprising identifying the test compound as a target compound if the modulation profile of the test compound conforms to the target modulation profile; wherein the target modulation profile includes one or more TLR7-mediated cellular activities that are not detectably modulated by a target compound; wherein the determining the modulation profile of a test compound comprises performing at least one assay for detecting modulation of a TLR7-mediated cellular activity.

Jurk et al., teach a method of screening for compounds for their potential to activate HEK293 cells that were transiently transfected with TLR cDNAs and a NF- κ B luciferase reporter plasmid (columns 2-3). The authors found that R-848 induced NF- κ B activation in HEK293 cells transfected with human TLR7 and TLR8. Thus, the authors conclude that TLR7 and TLR8 mediate the recognition of the same antiviral compound R-848. Jurk et al., also teach a method of screening for compounds that modulate a TLR7-mediated cellular activity (e.g. NF- κ B activation), disclose a testing assay and show that both TLR7 and TLR8 confer responsiveness to R-848.

15. Claims 1-2 and 5-7 are rejected under 35 U.S.C. 102(a) as being anticipated by Gibson et al. (Cell Immunol. 2002 Jul-Aug;218(1-2):74-86).

The claims recite as stated *supra*.

Gibson et al., teach a method of identifying a compound that selectively modulates at least one TLR7-mediated cellular activity. Gibson et al., teach agonists that stimulate human plasmacytoid dendritic cells (pDC) to produce a number of cytokines including TNF α , IP-10, IFN α , and IFN γ (p. 83, Figure 4). The authors show that certain compounds activate NF- κ B through TLR7 but not through TLR9 (seep. 78, Table 2). Therefore, in the absence of any evidence to the contrary, Gibson et al., anticipates the instant claims.

16. Claims 1-2 and 5-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Bauer et al., US Patent 6,943,240 (13 September 2005, benefit to 15 September 2000).

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The claims recite as stated *supra*.

Bauer et al., teach several methods of screening for ligands, inhibitors, agonists, and antagonists of TLR7 and signaling mediated by TLR7 (see column 14, lines 1-11; column 50, lines 4-65; column 61 line 13 to column 62 line 65; Example 21, column 123 line 63 to column 124, lines 46-67).

Conclusion

17. The prior art made of record and not relied upon in the instant Office Action is considered pertinent to applicant's disclosure.

- a. Ito et al., (J Exp Med. 2002 June 3; 195(11):1507-1512) teach differential induction of IFN α and IL-12 by TLR7 ligands in human blood dendritic cell subsets.

NO CLAIM IS ALLOWED.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cherie M. Woodward whose telephone number is (571) 272-3329. The examiner can normally be reached on Monday - Thursday 9:00am-7:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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